

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 116833	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International Application No. PCT/AU2003/001687	International Filing Date (day/month/year) 18 December 2003	Priority Date (day/month/year) 19 December 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61F 11/04, A61N 1/05		
Applicant COCHLEAR LIMITED et al		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheet(s).</p>
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input checked="" type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input checked="" type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand 10 March 2004	Date of completion of the report 5 April 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer A. ALI Telephone No. (02) 6283 2607

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

The International Preliminary Report on Patentability (Chapter II) has been drawn up in respect of the entire international application but the International Preliminary Examining Authority is of the opinion that the application does not appear to comply with the requirements of unity of invention as set forth in the PCT regulations (Article 34(3), Rule 68(1) PCT).

The separate groups of invention are:

1. Claims 1-7, 11. It is considered that a seal that is pierceable by a stiffening element but which at least substantially seals the lumen following removal of the stiffening element therefrom comprises a first "special technical feature".
2. Claims 12-19. It is considered that a sealing member mountable to the stiffening member, wherein the stiffening member is movable relative to the orifice of the lumen between a first position in which the sealing member mountable thereon does not seal the lumen and a second position in which the sealing member at least substantially seals the lumen comprises a second "special technical feature".
3. Claims 20-24. It is considered that a compression member adjustable between a first configuration in which the compression member does not compress a portion of the lumen and a second configuration in which the compression member does compress the lumen comprises a third "special technical feature".

See supplemental sheet.....

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-7, 11-33	YES
	Claims 8-10	NO
Inventive step (IS)	Claims 1-7, 11-33	YES
	Claims 8-10	NO
Industrial applicability (IA)	Claims 1-33	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

NOVELTY (N) AND INVENTIVE STEP (IS)

Claims 8-10

WO 2002/028473 A1 (COCHLEAR LIMITED) 11 April 2002

This document clearly discloses a plug member that is positionable within an orifice of a lumen of an elongate member of an implantable tissue-stimulating device. Refer to the plug 19 shown in figure 1. These claims therefore lack novelty and an inventive step.

Claims 1-7, 11-33

These claims are novel and inventive as no prior art document discloses a lumen being able to receive a stiffening element through the orifice, and a seal that is pierceable by the stiffening element but which at least substantially seals the lumen following removal of the stiffening element therefrom.

INDUSTRIAL APPLICABILITY (IA)

The subject matter of the claims finds application in the medical/human necessities industry.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claim 9 does not define any features that characterise the plug member. It merely defines a plug member "that is positionable" within an orifice and therefore relies on the result to be achieved to define its features.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of IV

4. Claims 25-29. It is considered that the lumen having at least one first portion of a first diameter and at least one second portion having a diameter less than that of said at least one first portion comprises a fourth "special technical feature".
5. Claim 30. It is considered that at least a portion of the lumen coated with a layer of material that swells following exposure to bodily fluids comprises a fifth "special technical feature".
6. Claims 31-33. It is considered that the lumen in the region adjacent the orifice decreases in diameter away from the orifice into the elongate member for a length comprises a sixth "special technical feature".

NOTE : Claims 8-10. These claims define a plug member (that is positionable within an orifice of a lumen). No special technical features are defined that could be considered to characterise the plug member. In fact an example of such a plug is clearly disclosed in WO 2002/028473.

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

Since all the inventions were searched, the International Preliminary Examination Report is based on all claims.